DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB 24 2006

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Re: VESIcare
Docket No.: 2005E-0235

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 6,017,927, filed by Yamanouchi Pharmaceutical Co., Ltd., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for VESIcare, the human drug product claimed by the patent.

The total length of the regulatory review period for VESIcare is 2,027 days. Of this time, 1,325 days occurred during the testing phase and 702 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: May 5, 1999.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 5, 1999.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 19, 2002.

   FDA has verified the applicant's claim that the new drug application (NDA) for VESIcare (NDA 21-518) was initially submitted on December 19, 2002.

3. The date the application was approved: November 19, 2004.

   FDA has verified the applicant's claim that NDA 21-518 was approved on November 19, 2004.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Susan J. Mack
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